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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number:
	)	
	)	
	)	
	)	
	)	
[ ]	)	P11-0483, P11-0487, P11-0527, P11-0528,
	)	P11-0529, P11-0530, P11-0532, P11-0533,
	)	and P11-0534
	)	
	)	
	)	
	)	
	)	
	)	

EPA SANITIZED

Consent Order, Consent Order for Contract Manufacturer,
and Determinations Supporting Consent Orders

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PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notices ("PMNs") P11-0483, P11-0487, P11-0527, P11-0528, P11-0529, P11-0530, P11-0532, P11-0533, and P11-0534 ("the PMN substances") submitted by [ ] ("the Companies"), to take effect upon expiration of the PMN review period. The Companies submitted the PMNs to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for the PMN substances requires the Companies to:

(1) Record and report [ ] impurities of the starting [ ] raw materials;

(2) Not exceed the maximum established levels of [

] impurities;

(3) Submit to EPA the results of certain triggered tests on the PMN substance P11-0483 and triggered fate test data on the PMN substance P11-0530 before manufacturing or importing an aggregate of [ ] kilograms (kg) (Tier 1), [ ] years [ ] months after the Company signed this Consent Order (Tier 2), [ ] kg (Tier 3) and, [ ] kg (Tier 4) of the PMN substances P11-0487, P11-0530, P11-0533, and P11-0534 combined;

(4) Limit the annual production volume for the PMN substances, P11-0487, P11-0530, P11-0533, and P11-0534 to [ ] kg each;

(5) Use the PMN substances P11-0483, P11-0527, P11-0528, P11-0529, and P11-0532 as chemical intermediates as described in the PMNs (to manufacture P11-0487, P11-0530, P11-0533, and P11-0534) and to manufacture [

];

(6) Use the chemical substances P11-0487, P11-0530, P11-0533 and P11-0534 only as surfactants for [ ] applications as described in the PMNs;

(7) Not use the PMN substances in any consumer spray applications;

(8) Distribute the PMN substances only to a person that agrees to follow the same restrictions (except for testing requirements listed in the Testing section of the Consent Order);

(9) Comply with the Release to water provisions;

(10) Incinerate all waste containing any of the PMN substances from manufacturing and processing (except for the PMN materials/waste that will be recycled and reused in

manufacturing of the PMN substances or products made from the PMN substances) in an incinerator with combustion temperature of minimum 1000 degrees C and residence time of minimum 2 seconds; and

(11) Maintain certain records.

A Consent Order for Contract Manufacturers is attached (Attachment C) to extend these requirements to the identified Contract Manufacturers. The Contract Manufacturers must keep records of quantities manufactured, but the Companies must submit to EPA all information required in the Consent Order.

III. CONTENTS OF PMN

By signing this Order, the Companies represent that they have carefully reviewed this document and agree that all information herein that is claimed as confidential by the Companies is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order):

Companies' identities; chemical identities; impurities; synonyms; production volumes; specific use; operation descriptions, including exposure and release estimates; and physical/chemical properties.

Chemical Identity:

Specific:

P-11-0483 - [ ],

P-11-0487 - [

],

P-11-0527 - [

],

P-11-0528 - [

],

P-11-0529 - [

].

P-11-0530 - [

],

P-11-0532 - [

],

P-11-0533 - [

], and

P-11-0534 - [

].

Generic:
P-11-0483, alkyl thiol;
P-11-0487, alkyl polyamide;
P-11-0527, substituted fluoroalkane;
P-11-0528, fluorinated thiol;
P-11-0529, fluorinated monomer;
P-11-0530, fluoropolyacrylamide;
P-11-0532, polyfluoroalkyl amine;
P-11-0533, non-ionic fluorosurfactant; and
P-11-0534, anionic fluorosurfactant.

Use:
Specific:
P-11-0483 – [ ].

P-11-0487 – [ ].

P-11- 0527 - [ ].

P-11-0528 - [ ].

P-11-0529 - [ ]

P-11-0530 - [ ].

P-11-0532 - [ ].

P-11- 0533 and P-11-0534 – [

].

Generic: P11-0487, P11-0530, P11-0533 and P11-0534 - surfactants

P11-0483, P11-0527, P11-0528, P11-0529, and P11-0532 - chemical intermediates

Maximum 12-Month Production Volume: (kg/year)
P-11-0483 – [ ]
P-11-0487 – [ ]
P-11- 0527 – [ ]
P-11- 0528 – [ ]
P-11- 0529 – [ ]
P-11- 0530 – [ ]
P -11- 0532 – [ ]
P-11- 0533 - [ ]
P-11- 0534 - [ ]

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

Based on the properties of the PMN substances and test data on analogous perfluorinated chemicals and potential perfluorinated degradation products such as perfluorooctanoic acid

(PFOA), perfluorooctanesulfonate (PFOS), perfluorohexane sulfonate (PFHS), and 1H,1H,2H,2H-perfluoroocanesulfonic acid, EPA has identified human health and ecotoxicity concerns.

Human Health Effects Summary:

Based on the analysis of the available test data for surfactant properties of analogous substances and the degradation products of the PMN substances (P11- 0483, P11-0487, P11-0527, P11-0528, P11-0529, P11-0530, P11-0532, P11-0533, and P11-0534), EPA has human health concerns for irritation to skin, eyes, lungs, mucous membranes, and lung toxicity if inhaled. Toxicity studies on PFOA and PFOS indicate liver toxicity, blood toxicity, male reproductive toxicity, immunosuppression, and oncogenicity. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife.

Ecotoxicity and Environmental Effects Summary: All PMN substances subject to this Order, P11- 0483, P11-0487, P11-0527, P11-0528, P11-0529, P11-0530, P11-0532, P11-0533, P11-0534 and/or degradation products have been identified as having a potential concern for ecotoxicity. Based on EcoSAR analysis of test data on analogous substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed the identified concentrations of concern (COC). Based on data for analogous perfluorinated chemicals, perfluorooctanoic acid (PFOA), perfluorooctanesulfonate (PFOS), and perfluorohexane sulfonate (PFHS), EPA has determined that the PMN substances and their degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds ("PBT"). The presumed perfluorinated degradants for the PMN substances include perfluorohexanoic acid (PFHxA). Biodegradation and photolysis tests

of analogous substances to PFOA and PFOS indicate little or no biodegradation or photolysis of perfluoroalkyl compounds.

Bioaccumulation concerns are based on concerns raised by the measured presence of certain perfluoroalkyl compounds with longer carbon chain length, including PFOA, PFOS, and PFHS in wildlife and in human blood samples. Potential risks to the environment are controlled by the

Disposal and Release to Water restrictions are detailed in the Consent Order.

Exposure and Environmental Release Summaries:

Manufacturing will take place at the following [ ] sites:

[

]

Waste to the environment from manufacturing [ ] and processing (that contain the PMN substances) will be incinerated. Processing [ ] will take place at [ ]. Occupational dermal and inhalation exposures are [ ]. Use as [

].

Environmental releases during use [ ] which is considered dispersive use are from disposal of [ ], and from disposal to POTW or to surface water of [ ]

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substances and their potential degradation products. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substances and potential degradation products.

(b) In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances may present an unreasonable risk of injury to human health and the environment.

(c) In light of the estimated production volume of, and human exposure to, the PMN substances and potential degradation products, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substances will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and potential degradation products.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Companies from exceeding the specified production volumes unless the Companies submit the information described in the Testing section of this Order for P11-0483 and P11-0530 in accordance with the conditions specified in the Testing section.

In addition, the Companies shall not manufacture or cause, encourage or suggest that a [ ] manufacturer manufacture the PMN substances unless a routine testing of the [ ] starting raw material for [ ] impurities by the Companies or as evidenced by a Certificate of Analysis from the raw material supplier, meets the established purity level as specified in Table 1 and Table 2 of this Order. Further, the Companies or the raw material supplier will annually test the [ ] starting raw material for [ ], including establishing calibration curves where the level of quantification desired is [ ].

If, at any point, the PMN substances [ ] that are related to the PMN substances regulated under this Consent Order but are regulated separately through a [ ] are withdrawn by the Companies from PMN review, P11-0487, P11-0530, P11-0533, and P11-0534 will be subject to all testing (triggered) required in the [ ]. In addition, P11-0530 will be subject to all tests required for P11-0483 in the case of [ ] withdrawal. The testing triggers will be calculated at the time of the withdrawal, starting from the beginning of the manufacturing.

Pended Testing.

The following pended testing on the PMN substances P11-0487, P11-0527, P11-0528, P11-0529, P11-0532, P11-0533, and P11-0534, would be necessary to evaluate the environmental effects:

> All the triggered tests listed in the Testing section of this Consent Order for P11-0483 and P11-0530 plus aerobic and anaerobic transformation in soil tests (OECD 307), phototransformation of chemicals (Draft OECD Guideline on soil surfaces-2 soils, Jan. 2002), simulation test-aerobic sewage treatment (activated sludge units) (OECD 303A), and aerobic and anaerobic transformation in aquatic sediment systems (OECD 308).

P11-0530 will have the following tests pended: phototransformation of chemicals (Draft OECD Guideline on soil surfaces-2 soils, Jan. 2002), simulation test-aerobic sewage treatment (activated sludge units) (OECD 303A), and aerobic and anaerobic transformation in aquatic sediment systems (OECD 308).

No consumer spray application of any of the PMN substances (P11-0487, P11-0530, P11-0533, and P11-0534) is allowed until the following tests of all PMN compounds for health effects are conducted by the Companies, submitted to and evaluated by EPA, and the use in consumer spray application is approved by EPA: acute inhalation test, OPPTS 870.1300, and a 90-day inhalation study, OPPTS 870.3465, with a post-exposure observation period of up to 3 months and bronchoalveolar lavage fluid (BALF) analysis. EPA has determined that the test results could allow the Agency to consider consumer spray application of the PMN substances.

The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information. EPA expects that protocols would be submitted prior to any additional toxicological or ecological testing. Due to the limited water solubility of some of these substances and consequent analytical difficulties, some modification of the protocols may be necessary. These and other modifications will be agreed upon between EPA and the Companies.

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the following chemical substances;

P-11-0483 - [
],

P-11-0487 - [
], P-11-0527 - [
], P-11-0528 - [
], P-11-0529 - [
],

P-11-0530 - [
], P-11-0532 - [
], P-11-0533 - [
], and P-11-0534 - [
],

submitted by [ ] ("the Companies"), to take effect upon expiration of the PMN review period, except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substances are exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Companies begin commercial manufacture of the PMN substances for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Companies begin to manufacture the PMN substances for use in the United States, no further activity by the Companies involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At this point, the requirements of this Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to the terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR

720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substances when they are produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when they are manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substances, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substances when they are imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Companies have obtained for the PMN substances a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Companies are prohibited from manufacturing the PMN substances in the United States, for any non-exempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substances, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

CHEMICAL SYNTHESIS AND COMPOSITION

(a) Restrictions. The Companies shall not manufacture or cause, encourage or suggest that a [ ] manufacturer manufacture the PMN substances unless testing of the [ ] starting raw material by the Companies or as evidenced by a Certificate of Analysis from the raw material supplier, meets the established purity level as specified in Table 1 and Table 2 of this Order. If, a product that contained [ ] products was processed or manufactured in the equipment at the facility where the PMN substances are to be made, the Companies shall test the Initially Isolated Formulations of the PMN substances for the analytes specified in Table 3 of this Order to confirm that cross-contamination from the manufacture of the product with [ ] has not occurred. Testing shall be conducted upon initial commencement of manufacture and at least annually thereafter, until one year after the date of the last manufacture or processing of a product that contains [ ] products at that facility. No testing of Initially Isolated Formulations of the PMN substances will be required if [ ] have not been previously manufactured or processed or

were not manufactured or processed at the facility within one year of manufacturing or processing of the PMN substances. The Companies shall submit all test protocols to EPA for approval prior to initiating testing. Protocols should be submitted to the OPPT Document Control Office (7407M), 1200 Pennsylvania Ave, N.W., Washington, DC 20460; Attention: Program Manager, New Chemicals Program, Chemical Control Division. EPA will respond to the Companies within [ ] of receiving the written protocols. Absent a response from EPA within the [ ] window, the Companies are permitted to rely on its protocols until an EPA response is received. The Companies shall record the levels of impurities [ ] associated with the PMN substances manufactured by the Companies and/or the Contract Manufacturer, as specified below. The Companies shall record analytes present in the [ ], at each manufacturing facility using this raw material (as shown in Table 1). Further, the Companies will also annually record the analyte [ ] present in the [ ] starting raw material (as shown in Table 2). The Companies shall make its best effort to minimize these impurities. If any new manufacturing facilities are added, or the manufacturing process is significantly altered, then the PMN substances must be tested at commencement of these actions and annually thereafter.

(b) Reporting. The Companies shall test representative samples of the Initially Isolated Formulations of the PMN substances manufactured or imported by the Companies and/or the Contract Manufacturer to determine compliance with the requirements in paragraph (a). The Companies shall test the Initially Isolated Formulations of the PMN substances at each manufacturing facility both (1) at the initial commencement of non-exempt manufacture of the PMN substances at that facility, and (2) at least annually thereafter during every year in which

the PMN substances are manufactured at that facility or imported. If any new manufacturing facility is added, or if the process of manufacture of the PMN substances or any intermediate thereof is significantly altered, then the Initially Isolated Formulation of the PMN substances must be tested at commencement of these actions and annually thereafter, as set forth above. If the PMN substances are imported, the Companies shall obtain from the foreign manufacturer written documentation to certify that representative samples of the imported form of the PMN substances have been tested, consistent with the requirements of this paragraph (b) and determined to comply with the requirements of paragraph (a).

The Companies shall report the above testing to EPA at initial commencement of manufacture or import and again if any new manufacturing facility is added or if the process of manufacture of the PMN substances or any intermediate thereof is significantly altered. the Companies shall continue to report these impurity levels to EPA annually. This is consistent with the current annual reporting cycle [

]. In addition to the reporting for the Initially Isolated Formulations of the PMN substances itself, the Companies shall, for the [ ] starting raw material, annually report (1) the average values and the range of values, including outlying data, for the routine testing for the analytes specified in Table 1, and (2) the results of the annual testing for the analyte specified in Table 2.

TABLE 1: Chemicals to be Routinely Tested in [ ] Starting Raw Material

Analyte	CAS Number	Limit in []
[]	[ ]	[] minimum
[] []	[ ] [ ]	[]

TABLE 2: Chemicals to be Tested at least Annually in [ ] Starting Raw Material

Analyte	CAS Number	Limit in []
[]	[ ]	[]

TABLE 3: Chemicals to be Tested in the Initially Isolated Formulations of the PMN Substance

Analyte	CAS Number	Estimated Maximum in Initially Isolated Formulations of the PMN Substance
[] []	[ ] [ ]	[]
[]	[ ]	[]

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substances which reasonably supports the conclusion that the PMN substances presents a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification numbers for these substances and contain a statement that the substances are subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at *www.epa.gov/oppt/tsca8e*.

(b) Notice of Study Scheduling. The Companies shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study

required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of the persons at the Companies or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for each substances and a statement that the substances are subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to the triggered testing requirements of this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any toxicity study, the Companies must obtain approval of test protocols from EPA by submitting written protocols. Protocols must be submitted to the OPPT Document Control Office (7407M), 1200 Pennsylvania Ave. N.W., Washington, DC 20460; Attention: Program Manager, New Chemicals Program, Chemical Control Division. EPA will respond to the Companies within [] of receiving the written protocols. Absent a response from EPA within the [] window, the Companies are permitted to rely on its protocol until an EPA response is received. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. EPA approval of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Companies are prohibited from manufacturing or importing the PMN substances beyond the following time allowances or aggregate manufacture and import volumes ("the production limits"), unless the Companies either:

(1) conducts the following studies on the PMN substances and submits all final reports and underlying data in accordance with the conditions specified in this Testing section, or

(2) submits other relevant information (including test data conducted using alternate guidelines) to meet these requirements and EPA determines that this other information satisfies the testing requirements.

The following triggered testing on the PMN substance P11-0483 (Tiers 1, 3, and 4) and Tier 2 and Tier 4 triggered fate tests on the PMN substance P11-0530 will be required in the Consent Order 14 weeks before manufacturing or importing an aggregate of [ ] kilograms (Tier 1), [] years [] months (Tier 2), [] kilograms (Tier 3), and [] kilograms (Tier 4) of the PMN substances [ ] combined.

Tier 1 tests (for P11-0483 chemical substance)	[ ] kg
Pharmacokinetics study in rats and mice	(OPPTS 870.7485)
Combined repeated dose toxicity study with developmental/reproduction screening test, oral route, species to be determined by the results of the pharmacokinetics studies with modifications.	(OPPTS 870.3650 modified, OECD 421 modified)
Tier 2 tests (for P11-0530 chemical substance)	[] years [] months after the date the Company signed this Consent Order
Soil biodegradation study	(OECD 307)

Tier 3 (for P11-0483 chemical substance) [ ] kg

Fish 96-hr LC50 Flow-through method, analytical measurement of test substance, mean, measured test concentrations.	(OPPTS 850.1075)
Acute Daphnia Flow-through method, analytical measurement of test substance, mean, measured test concentrations.	(OPPTS 850.1010)
Algae Static method, analytical measurement of test substance, mean, measured test concentrations.	(OPPTS 850.5400)

Tier 4 test [ ] kg

Triggered testing (for P11-0483 chemical substance)

Avian Reproduction in bobwhite quail or mallard ducks for PMN compound.	(OPPTS 850.2300, OECD 206)

Triggered testing for P11-0530 chemical substance

Hydrolysis as a function of pH and temperature	(OPPTS 835.2130, OECD 111)
UV visible light absorption	(OPPTS 830.7050)
Direct Photolysis, if wavelengths greater than 290 nm are absorbed in the previous test	(OPPTS 835.2210)
Indirect Photolysis Screening Test	(OPPTS 835.05270)
Anaerobic biodegradability of organic compounds in digested sludge	(OECD 311/835.3420)
Degradation test	(Modified Semi Continuous Activated Sludge, SCAS, OPPTS Guideline 835.5045 or OECD 302A, or modified Zahn-Wellens method, OECD 302B, with analysis for degradation products - see EPA general guidance presented in Attachment D, Key

Elements of Biodegradation Testing of Fluorotelomer Based Chemicals. The Companies must analyze for the C6 and C7 possible degradants specified in Table 4 below)

Table 4. Potential PBT Environmental Metabolites/degradants to be analyzed.

Analyte	CAS Number
[]	[]
[]	[ ]
[]	[ ]
[]	[ ]
[]	[ ]
[]	[ ]
[]	[ ]
[]	[ ]

(e) Test Reports. The Companies shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA prior to exceeding the production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data

such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Companies are not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study because for example, alternative information would satisfy the requirements.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Companies may continue to manufacture and import the PMN substances beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Companies may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (e)(2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Companies.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Companies receive written notice that EPA finds that the data generated by a study are scientifically invalid, the Companies are prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Companies may continue to manufacture and import the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Companies' compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Companies may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA before exceeding the production limits as required by subparagraph (e)(3), the Companies shall comply with subparagraph (e)(3). If there is insufficient time for the Companies to comply with subparagraph (e)(3), the Companies may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Companies, in writing, within 6 weeks of receiving the Companies' report and data.

(ii) The Companies may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Companies, in writing, within 4 weeks of receiving the Companies' report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Companies become aware that circumstances clearly beyond the control of the Companies or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Companies remain prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) the Companies may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Companies or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Companies of its response, in writing, within 4 weeks of receiving the Companies' report. EPA's written response may either:

(i) allow the Companies to continue to manufacture and import the PMN substances beyond the applicable production limit, or

(ii) require the Companies to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the production limits, as required by subparagraph (e)(3), the Companies shall comply with subparagraph (e)(3). If there is insufficient time for the Companies to comply with subparagraph (e)(3), the Companies may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Companies, in writing, within 6 weeks of receiving the Companies' report and data, as to whether the Companies may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Companies in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Companies undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Companies must cease all manufacture, import, processing, distribution, use and disposal of the PMN substances, unless either:

(A) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Companies comply with such requirements as EPA's notice specifies; or

(B) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Companies submit to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Companies may continue to manufacture, import, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Order pending EPA's response to the Companies' written report. EPA will respond to the Companies, in writing, within 4 weeks of receiving the Companies' report. Within 2 weeks of receipt of EPA's written response, the Companies shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substances.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Companies must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Companies may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI of this Consent Order.

MANUFACTURING

(a)(1) Prohibition. The Companies shall not cause, encourage, or suggest the manufacture or import of the PMN substances by any other person, except as described in paragraph (b).

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under section 5(a)(2) of TSCA unless the Companies are notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Companies are so notified, subparagraph (a)(1) shall not expire until EPA notifies the Companies in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Companies shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substances of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substances. Such notice must also reference the publication of the SNUR for the PMN substances in either the Federal Register or the Code of Federal Regulations.

(4) Subparagraph (a)(2) shall not negate the effects of any fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2).

(b) Contract Manufacturer. Notwithstanding paragraph (a), the Companies may cause the Contract Manufacturer(s) identified in the PMN and listed in the Preamble of this Order to manufacture or import the PMN substances according to the following conditions (after this Order has been signed, the Companies may petition EPA pursuant to Section VI of this Order to include additional Contract Manufacturers):

(1) The Contact Manufacturer must be under contract to the Companies to manufacture or import the PMN substances solely for the Companies. The contract must specify the identity of the PMN substances, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Companies shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Consent Order should be submitted to the OPPT Document Control Office (7407M), 1200 Pennsylvania Ave. N.W., Washington, DC 20460; Attention: Program Manager, New Chemicals Program, Chemical Control Division. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for the Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture or import.

(3) If at any time, the Companies learn that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Companies shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substances, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substances, or unless the Companies are able to document each of the following:

(i) That the Companies have, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with the conditions specified in the Consent Order for Contract Manufacturer.

(ii) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Companies received from the Contract Manufacturer, in writing, a statement

of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(iii) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Companies have notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Companies shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substances, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture or import the PMN substances only upon written notification from the Agency.

c) The Companies and their Contract Manufacturer(s) shall not manufacture the PMN substances P11-0487, P11-0530, P11-0533, and P11-0534 beyond an annual manufacture and importation volume of [ ] each.

USE

The Companies shall:

(a) use the PMN substances P11-0483, P11-0527, P11-0528, P11-0529, and P11-0532 as [ ] described in the PMNs (to manufacture P11-0487, P11-0530, P11-0533, and P11-0534) and to manufacture [ ].

(b) use the PMN substances P11-0487, P11-0530, P11-0533, and P11- 0534 only as surfactants for [ ] applications under the scenarios described in the PMNs; and

(c) not use the PMN substances P11-0487, P11-0530, P11-0533, and P11- 0534 for consumer spray applications.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Companies shall notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substances is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substances, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. Except as provided in paragraph (c), the Companies shall distribute the PMN substances outside the Companies, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substances is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substances, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Comply with the same environmental release restrictions, required of the Companies

in the Disposal and Release to Water sections of this Order.

(3) Use the PMN substances P11-0483, P11-0527, P11-0528, P11-0529, and P11-0532 only as chemical intermediates described in the PMNs and to [

];

(4) Use the PMN substances P11-0487, P11-0530, P11-0533, and P11- 0534 only as surfactants for [ ] applications under the scenarios described in the PMNs; and

(5) Not use the PMN substances P11-0487, P11-0530, P11-0533, and P11-0534 for consumer spray applications.

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Companies may distribute the PMN substances outside the Companies for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substances may be distributed only to the Companies or a person who has given the Companies the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substances may occur only while the PMN substances is in the possession and control of the Companies or a person who has given the Companies the written agreement required by paragraph (b).

(3) A statement of the health hazards(s) and precautionary measure(s), if any, identified by the Companies for the PMN substance; the identity by which the PMN substance may be commonly recognized; a statement of the environmental hazard(s) and precautionary measure(s),

if any, identified by the Companies for the PMN substance; a statement of exposure and precautionary measure(s), if any, identified by the Companies for the PMN substance; and the name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures. The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substances, the Companies obtain knowledge that a recipient of the substances has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after paragraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substances (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Companies shall cease supplying the substances to that recipient, unless the Companies are able to document each of the following:

(1) That the Companies have, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substances without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Companies received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms,

or is aware of the terms of the significant new use rule for the PMN substances and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Companies obtain knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substances without submitting a significant new use notice to EPA, the Companies shall cease supplying the PMN substances to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substances to that recipient only upon written notification from the Agency.

(e) Sunset Following SNUR. (1) Paragraph (b)(2) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substances under section 5(a)(2) of TSCA, unless the Companies are notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Companies are so notified, paragraph (b)(2) of this Distribution section shall not expire until EPA notifies the Companies in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed. (2) When EPA promulgates a final SNUR for the PMN substances and paragraph (b)(2) of this Distribution section expires in accordance with subparagraph (e)(1), the Companies shall notify each person to whom it distributes the PMN substances of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substances. Such notice must also reference the publication of the SNUR for these PMN substances in either the Federal Register or the Code of Federal

Regulations. After promulgation of a SNUR and expiration of subparagraph (b)(2), such notice may substitute for the written agreement required in the introductory clause of paragraph (b); so that, if the Companies provide such notice to the persons to whom it distributes the PMN substances, then the Companies are not required to obtain from such persons the written agreement specified in paragraph (b).

DISPOSAL

The Companies shall dispose of the PMN substances and any waste containing the PMN substances from manufacturing and processing only as follows: incinerate the waste in an incinerator operating at the temperature of at least 1000 degrees C and a residence time of minimum of 2 seconds. Any tank or vessel washings, residues from transport vessels or tanks, and similar materials that are captured and retained in the normal course of manufacturing and processing for re-use in manufacturing of the PMN substances or products made from the PMN substances are exempt from this method of disposal.

This provision does not supersede or preempt any applicable federal, state, and local laws and regulations if those laws are more stringent than the requirements below.

RELEASE TO WATER

This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.)

the Companies are prohibited from any predictable or purposeful release of the PMN substances, or any manufacturing or processing waste streams containing any of the PMN substances to the waters of the United States, except [

].

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Companies become aware that the PMN substances may present a risk of injury to human health or the environment (or is so notified by EPA), the Companies must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS") for the PMN substances, as described in 40 CFR section 721.72(c), within 90 days from the time the Companies become aware of the new information. If the PMN substances are not being manufactured, imported, processed, or used in the Companies' workplace, the Companies must add the new information to an MSDS before the PMN substances are reintroduced into the workplace.

(b) the Companies must ensure that persons who will receive the PMN substances from the Companies (including any Contract Manufacturer(s) (as described in paragraph (b) of the Manufacturing section of this Order), or who have received the PMN substances from the Companies within 5 years from the date the Companies become aware of the new information

described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Companies become aware of the new information.

III. RECORDKEEPING

(a) Records. The Companies shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Companies. Any amounts or batches of the PMN substances eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Companies maintain, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Companies maintain, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Companies shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (3)

and (4) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting compliance with the Chemical Synthesis and Composition;

(3) Records documenting the manufacture and importation volume of the PMN substances and the corresponding dates of manufacture and import;

(4) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Companies directly sell or transfers the PMN substances, the date of each sale or transfer, and the quantity of the substances sold or transferred on such date;

(5) Records documenting the address of all sites of manufacture, import, processing, and use;

(6) Records documenting compliance with any applicable manufacturing, processing, use, disposal and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(7) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substances disposed. Where the estimated disposal volume is not known to the Companies and is not reasonably ascertainable by the Companies, the Companies must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;

(8) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(9) Copies of any Transfer documents and notices required by the Successor Liability section of this Order, if applicable; and,

(10) The Companies shall keep a copy of this Order at each of its sites where the PMN substances is manufactured, imported, processed, or used.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Companies and its Contract Manufacturer, if applicable, and not to activities of the Companies' customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Companies are not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Companies. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances

associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Companies in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances that are collected during the manufacture or processing of the PMN substances;

(5) Records required by the Recordkeeping section of this Order; and/or,

(6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Companies shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Companies' response shall be in writing. To the extent the information is known to or reasonably ascertainable by the Companies at the time of the request, the Companies' response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Companies submit to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Companies' rights and obligations under this Order may be transferred when the Companies transfer its interests in the PMN substances, including the right to manufacture the PMN substances, to another person outside the Companies (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Companies to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Companies pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substances.

(2) After NOC. If the transfer from the Companies to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Companies who has acquired the Companies' full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Companies, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Companies in the PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substances, including the right to manufacture the PMN substances, from the Companies to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Companies shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Companies shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances

is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Companies to the Successor in Interest.

(e) Liability.

(1) The Companies shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Companies after the effective date of the transfer for actions taken, or omissions made, during the time in which the Companies manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Companies to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured and imported by the Companies up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Companies may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substances.

In addition, the Companies may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Companies waive their rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Companies as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Companies may have under TSCA.

(b) CBI Brackets. By signing this Order, the Companies represent that it have carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Companies (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

19 March 2013
Date

Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

11 April 2013
Date

Name: [ ]
Title: [ ]
Company: [ ]

11 April 2013
Date

Name: [ ]
Title: [ ]
Company: [ ]

ATTACHMENT A

DEFINITIONS

Note: The attached Order may not contain some of the terms defined below.

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substances or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Companies, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II of this Consent Order and in the Consent Order for Contract Manufacturer.

"Final Formulation of the PMN substance" means the formulated dispersion of the PMN substance in the form in which it is sold to customers outside the Companies or transferred to a different business unit within the Companies. The term does not include intermediate dilutions of the PMN substance that are intended only for use within the Companies for further dilution prior to sale.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Initially Isolated Formulations of the PMN substance" means a common intermediate PMN formulation, as it exists when first produced and isolated after the polymer manufacturing process, that can be further processed or repackaged at the direction of the Companies to result ultimately in one or more final formulations of the PMN substance.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substances and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Companies relevant to this Order.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol, or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be neither human exposure to nor environmental release of the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Companies did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substances, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substances, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Companies, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substances(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Successor in Interest	
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

**NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)**

Successor's Technical Contact

Address

City, State, Zip Code

Phone